HKEX published additional guidance specific to biotech companies

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Introduction

Since 30 April 2018, pre-revenue Biotech Companies[1] have been permitted to list under Chapter 18A of the Rules Governing the Listing of Securities (Listing Rules) on The Stock Exchange of Hong Kong Limited (HKEx), being one of the three new listing chapters introduced under the new listing regime in April 2018. After two years' implementation of the new listing regime for pre-revenue Biotech Companies, a total number of 18 pre-revenue Biotech Companies have been listed under Chapter 18A of the Listing Rules as of 31 May 2020, raising HK$43.9 billion. The HKEX has recently published additional guidance materials for Biotech Companies providing prospective issuers and the market with more clarity on the requirements for listing and required disclosures. Below are some highlights of these guidance materials:

One New Guidance Letter and Two Updated Guidance Letters

New Guidance Letter – GL107-20

HKEX recently published a new Guidance Letter – GL107-20 in relation to "Disclosure in listing documents for Biotech Companies" providing detailed guidance on disclosure in listing documents for Biotech Companies. Please refer to the section headed "Details of New Guidance Letter – GL107-20" below for details.

Updated Guidance Letter – GL92-18

HKEX also published an updated guidance letter GL92-18 in relation to "Suitability for Listing of Biotech Companies" which, among other things:

- R&D of Core Products – provided clarifications relating to research and development (R&D) of a Core Product[2] which is in-licensed or acquired from third parties and the circumstances under which a commercialised Biotech Product in a given market for specified indications can be regarded as a Core Product;
- Use of proceeds – allowed flexibility for medical device companies to meet the requirement of a Biotech Company's primary reason for listing ie to raise funds for R&D to bring its Core Products to commercialisation taking into account their business plan and development stage of the pipeline products;
- "Other Biotech Products" category – streamlined and consolidated guidance on the factors that the HKEX will consider a Biotech Product to fall under "Other Biotech Products" under Chapter 18A of the Listing Rules[3];
- Subscription of shares by existing shareholders – clarified under what circumstances could an existing shareholder of a Biotech Company subscribe for additional shares in the IPO[4], for example, existing shareholders holding less than 10% equity interests in a Biotech Company may subscribe for shares in the IPO as cornerstone investor or placee subject to no preferential treatment confirmations, and existing shareholders holding 10% or more equity interests may subscribe for shares in the IPO as cornerstone investor, provided that the public float requirements under the Listing Rules are complied with; and
- Clawback mechanism – included guidance that any waiver from the clawback mechanism under Practice Note 18 to the Listing Rules will be considered on a case-by-case basis based on the specific facts and circumstances.

Updated Guidance Letter – GL85-16

HKEX also published an updated guidance letter GL85-16 in relation to "Placing to connected clients, and existing shareholders or their close associates, under the Rules" providing, among other things, additional clarification that the Existing Shareholders Conditions under paragraph 4.20 therein, such as an existing shareholder being interested in less than 5% of the applicant's voting rights before listing on HKEX, an existing shareholder not being a core connected person or its close associates, an existing shareholder not having the power to appoint directors or any other special rights, etc., no longer apply to Biotech Companies.

Details of New Guidance Letter – GL107-20

KEY AREAS	DISCLOSURE/GUIDANCE
Summary Section	Besides the basic disclosure requirements applicable for all applicants and some drafting and language principles, Biotech Companies are also required to disclose scientific description of biotech technology, key clinical data of Core Products, development timetable of Core Products, etc., and risk factor specific to a Biotech Company highlighting failure of its R&D may have a material adverse impact on its prospect.
Competitive landscape and addressable market	Disclose competitive landscape of Biotech Company's Core Products and other key pipeline products in targeted markets; material information on the relevant addressable market of Core Products and other key pipeline products rather than the overall market; and a comparison between Biotech Companies' products and direct competing products in certain major areas
Communication with Competent Authorities	Disclosure of material communication with the relevant Competent Authority[5] (where there is such communication) should include all meaningful data including whether the relevant Competent Authority has raised material concerns or objections towards the completed or ongoing clinical trials. If there is no such communication, a negative statement should be disclosed
Commercialised Core Products	In the case of a Core Product which has been commercialised in a given market for specified indication and the Biotech Company intends to apply a portion of the listing proceeds to expand the indications of the commercialised Biotech Product or launch it in another market, disclose a breakdown of the funds to support R&D and more details including resources required to support further studies; and their importance in advancing the Core Product
Core Products and advanced pipeline candidates classified and regulated as orphan medicines and/or innovative therapies	**Drug pathway classification** • disclose the basis for drug candidates to qualify in a particular regulatory pathway, the exemptions granted and the advantages therein for the drug products **Regulatory strategy** • disclose the commercialisation plan and/or market strategy to be taken for a particular drug product including timeline of next regulatory milestones **Collaboration** • define the calibre and experience of participating research institutions in a collaboration, material terms and conditions of the collaboration and ownership of the intellectual property rights, if applicable
Pipeline products	• disclose the origins (ie in-licensing or internally-developed) and the jurisdiction rights pertaining to the Biotech Products • highlight pipeline product that is strategically or commercially critical to the Biotech Company; or that the Biotech Company intends to apply a significant portion of listing proceeds to it even if it has not been developed beyond the concept stage
Valuation	• disclose valuation of each round of pre-IPO investments and explain material fluctuations in valuation
Sophisticated Investors[6]	• disclose material information on Sophisticated Investors

KEY AREAS	DISCLOSURE/GUIDANCE
Net liabilities[7]	• disclose in the Summary and Risk Factor sections if the Biotech Company incurred net liabilities during the track record period as a result of significant fair value change of convertible financial instruments and that they will be fully converted upon listing, therefore turning into a net assets position
Burn rate	• disclose in the Summary and other relevant sections: – a reasonable period of time, with basis, that a Biotech Company can maintain its viability with existing cash balance with and without the IPO proceeds – when the Biotech Company expects to raise its next round of financing based on its burn rate
Contractual arrangements	Biotech Companies should refer to listing decision LD43-3 if they adopt contractual arrangements

Comment

As the world's second largest biotech fundraising hub, the HKEx has seen increased interest from global institutions and the retail market towards Chapter 18A of the Listing Rules over the past two years. Therefore, it is welcoming to see that the updated guidance materials provide more clarity on the listing requirements and the level of disclosure expected by the HKEx from pre-revenue Biotech Companies so that better protection can be provided to investors from the risks associated with their investment in such companies.

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Notes

1. "Biotech Company" means a company primarily engaged in the research and development, application and commercialisation of biotech products, processes or technologies) seeking listing under Chapter 18A of the Listing Rules. For details please refer to Chapter 18A of the Listing Rules.
2. "Core Product" means a regulated product that alone or together with other regulated products forms the basis of a Biotech Company's listing application under Chapter 18A of the Listing Rules. For details please refer to Chapter 18A of the Listing Rules.
3. Previously HKEX FAQ No. 035-2018 and withdrawn in April 2020.
4. Previously HKEX FAQ No. 038-2018 and withdrawn in April 2020.
5. "Competent Authority" means the US Food and Drug Administration, the China Food and Drug Administration and the European medicines Agency and other national or supranational authority recognised by the HKEX at its discretion in individual cases. For details please refer to Chapter 18A of the Listing Rules.
6. Please refer to paragraph 3.2(g) of updated guidance letter GL92-18 for examples of types of investors which would generally be considered as a "Sophisticated Investor" by HKEX which are for illustrative purposes only and the HKEX will assess whether an investor is considered as a "Sophisticated Investor" on a case by case basis.
7. GL86-16: "Guidance on producing simplified listing documents relating to equity securities for new applications" has recently been updated with guidance on disclosure for a change in a net liabilities position to a net assets position as a result of conversion of convertible financial instruments upon listing which is applicable to all applicants including Biotech Companies.

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